

Dock No. PL-1888

Applicant Quirkard, et al

Serial No. 09/232,498 Filed 1/15/99

Receipt is hereby acknowledged of the

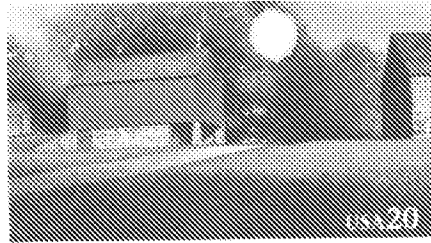
IPS form PTD 1449 and transmittal
in duplicate (with references)

Dated Aug. 11, 1999

Filed in connection with the above case.

COMMISSIONER OF PATENTS
AND TRADEMARKS





FISH & NEAVE
1251 AVENUE of the AMERICAS
NEW YORK, N.Y. 10020



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Appln. : 09/232,488
Applicants : Donna E. Prunkard and Donald C. Foster
Filed : January 15, 1999
Examiner : Unassigned
Art Unit : 1632
Patent : 5,639,940
Patentee : Ian Garner, Michael A. Dalrymple, Donna E.
Prunkard and Donald C. Foster
Assignee : Pharmaceutical Proteins, Ltd., and ZymoGenetics,
Inc.
Issued: : June 17, 1997
Application : 08/206,176
Filed : March 3, 1994
For : PRODUCTION OF FIBRINOGEN IN
TRANSGENIC ANIMALS

New York, New York
August 11, 1999

Hon. Assistant Commissioner
for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER FOR
INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the
above-identified application. This Statement is submitted:

- ☐ within three months of the application filing date;
- ☒ more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Commissioner is hereby authorized to charge payment of the fee to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

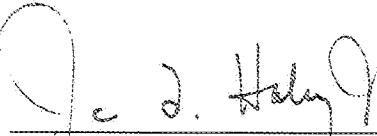
Respectfully submitted,

I hereby certify that this
Correspondence is being
Deposited with the U.S.
Postal Service as First
Class Mail in an Envelope
Addressed to: ASSISTANT
COMMISSIONER OF PATENTS
WASHINGTON D.C. 20231, on

4/11/05
EXHIBIT ENVELOPE

Name of Person Signing

Signature of Person Signing



James F. Haley, Jr. (Reg. No. 27,794)

Attorney for Applicants

c/o FISH & NEAVE

1251 Avenue of the Americas

New York, New York 10020-1104

Tel.: (212) 596-9000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Reissue Appln. : 09/232,488

Applicants : Donna E. Prunkard and Donald C. Foster

Filed : January 15, 1999

Examiner : Unassigned

Art Unit : 1632

Patent : 5,639,940

Patentee : Ian Garner, Michael A. Dalrymple, Donna E.
Prunkard and Donald C. Foster

Assignee : Pharmaceutical Proteins, Ltd., and ZymoGenetics,
Inc.

Issued: : June 17, 1997

Application : 08/206,176

Filed : March 3, 1994

For : PRODUCTION OF FIBRINOGEN IN
TRANSGENIC ANIMALS

New York, New York
August 11, 1999

Hon. Assistant Commissioner
for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §§ 1.56 AND 1.97

Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicants, through their attorney, make of record the documents listed below. A completed Form PTO-1449 listing all of the documents is enclosed herewith.

Applicants respectfully request that the documents listed below be (1) fully considered by the Examiner during the course of the examination of this application and (2) printed on any reissue patent issuing from this application. Applicants also request that a copy of the enclosed Form PTO-1449 duly initialed by the Examiner be forwarded to the undersigned with the next communication.

U.S. Patents

| | | |
|--------------|----------------------|-------------------|
| Meade et al. | Patent No. 4,873,316 | October 10, 1989 |
| Rosen | Patent No. 5,304,489 | April 19, 1994 |
| Clark et al. | Patent No. 5,366,894 | November 22, 1994 |

Foreign Patents

| | | |
|-------|-------------|------------------|
| World | WO 88/00239 | January 14, 1988 |
| World | WO 90/05188 | May 17, 1990 |
| World | WO 91/03216 | June 13, 1991 |
| World | WO 92/11358 | July 9, 1992 |
| World | WO 92/11757 | July 23, 1992 |

Other Documents

Behringer et al. (1989) "Synthesis Of Functional Human Hemoglobin In Transgenic Mice" Vol. 245, Science, pp. 971-973.

Binnie et al. (1993) "Characterization Of Purified Recombinant Fibrinogen: Partial Phosphorylation Of Fibrinopeptide A" Vol. 32, Biochemistry, pp. 107-113.

- Bolyard, M.G., et al., "Expression In Escherichia Coli Of The Human Fibrinogen B β Chains And Its Cleavage By Thrombin," Vol. 73, Blood, pp. 1202-1206.
- Burdon et al. (1991) "Expression Of A Whey Acidic Protein Transgene During Mammary Development" Vol. 266, No.11, The Journal of Biological Chemistry, pp. 6909-6914.
- Chung, Dominic W., et al.(1983), "Characterization Of A Complementary Deoxyribonucleic Acid And Genomic Deoxyribonucleic Acid For The β Chain Of Human Fibrinogen," Vol. 22, Biochemistry, pp. 3244-3250.
- Chung et al. (1983) "Characterization Of A Complementary Deoxyribonucleic Acid Coding For The γ Chain Of Human Fibrinogen" Vol. 22, No. 13, Biochemistry, pp. 3250-3256.
- Chung et al. (1990) "Nucleotide Sequences Of The Three Genes Coding For Human Fibrinogen" Vol. 201, Adv. Exp. Med., pp. 39-48.
- Clark et al. (1987) "Pharmaceuticals From Transgenic Livestock" Vol. 5, Tibtech, pp. 20-24.
- Clark et al. (1989) "Expression of human anti-hemophilic factor IX in the milk of transgenic sheep" Vol. 7, Bio/Technology, pp. 487-492.
- Clark et al. (1992) "Rescuing Transgene Expression By Co-Integration" Vol. 10, Bio/Technology, pp. 1450-1454.
- Danishefsky, K., et al.(1990), "Intracellular Fate Of Fibrinogen B β Chain Expressed In COS Cells," Vol. 1048, Biochem. Biophys. Acta, pp. 202-208.
- Darnell et al. Molecular Cell Biology abstract "The Organization Of DNA Differs Greatly In Prokaryotic and Eukaryotic Cells", p. 137 (Scientific American Books 1986).
- DiTullio et al. (1992) "Production Of Cystic Fibrosis Transmembrane Conductance Regulator In The Milk Of Transgenic Mice," Vol. 10, Bio/Technology, pp. 74-77.
- Dobrovolsky et al. (1993) "Human γ -Interferon Expression In The Mammary Gland Of Transgenic Mice" Vol. 319, FEBS Letters, pp. 181-184.
- Drohan et al. (1994) "Inefficient Processing Of Human Protein C In The Mouse Mammary Gland" Vol. 3, Transgenic Research, pp. 355-364.

Farrell, D.H. et al. (1994), "Binding Of Recombinant Fibrinogen Mutants To Platelets," Vol. 269, J. Biol. Chem., pp. 226-231.

Farrell et al., (1991) "Recombinant Human Fibrinogen And Sulfation Of The γ ' Chain" Vol. 30, No. 39, Biochemistry, pp. 9414-9420.

Greenberg et al., (1991) "Expression Of Biologically Active Heterodimeric Bovine Follicle-Stimulating Hormone In Milk Of Transgenic Mice" Vol. 88, Biochemistry, pp. 8327-8331.

Grosschedl, R., et al. (1984), "Introduction Of A μ Immunoglobulin Gene Into The Mouse Germ Line; Specific Expression In Lymphoid Cells And Synthesis Of Functional Antibody," Vol. 88, Cell, pp. 647-658.

Hartwig, R. et al. (1991), "Studies On The Assembly And Secretion Of Fibrinogen," Vol. 266 J. Biol. Chem., pp. 6578-6585.

Hennighausen, Lothar (1990) "The Mammary Gland As A Bioreactor: Production Of Foreign Proteins In Milk" Vol. 1, Protein Expression And Purification, pp. 3-8.

Hurtley et al., (1989) "Protein Obligomerization In The Endoplasmic Reticulum" Vol. 5, Annu. Rev. Cell Biol., pp. 277-307.

Lee, S.H., et al. (1994), "Production Of Biomedical Proteins In The Milk Of Transgenic Dairy Cows; The State Of The Art," Vol. 29, J. Controlled Release, pp. 213-221.

Lord, Susan T. (1980), "Expression Of A Cloned Human Fibrinogen cDNA In Escherichia Coli: Synthesis Of An A Alpha Polypeptide," Vol. 4, DNA, pp. 33-38.

Lord, Susan T., et al. (1989), "Expression Of A Fibrinogen Fusion Peptide In Escherichia Coli: A Model Thrombin Substrate For Structure/Function Analysis," Vol. 73, Blood, pp. 166-171.

Massoud et al. (1996) "The Deleterious Effects Of Human Erythropoietin Gene Driven By The Rabbit Whey Acidic Protein Gene Promoter In Transgenic Rabbits" Vol. 45, Ann Zootech, pp. 1-9.

McClenaghan et al. (1995) "Secretory Proteins Compete For Production In The Mammary Gland Of Transgenic Mice" Vol. 310, Biochemical Journal, pp. 637-641.

Mishina et al. (1986) "Molecular Distinction Between Fetal And Adult Forms Of Muscle Acetylcholine Receptor" Vol. 321, Nature, pp. 406-411.

Morcöl et al. (1994) "The Porcine Mammary Gland As A Bioreactor For Complex Proteins" Vol. 721, Recombinant DNA Technology II, pp. 218-233

Nicoll et al. (1965) "Estimates Of Parenchymal, Stromal, And Lymph Node Deoxyribonucleic Acid In Mammary Glands Of C311/Crg1/2 MICE" Vol. 4, No. 9, Life Sciences, pp. 993-1001.

Palmiter, Richard D., et al. (1985), "Transgenic Mice," Vol. 41, Cell, pp. 343-345.

Pittius et al., (1988) "A Milk Protein Gene Promoter Directs The Expression Of Human Tissue Plasminogen Activator cDNA To The Mammary Gland In Transgenic Mice" Vol. 85, Biochemistry, pp. 5874-5878.

Prunkard et al. UCLA Symposia on Molecular and Cellular Biology, "High Level Secretion Of Recombinant Human Fibrinogen In BHK Cells Is Limited By A Post-Transcriptional Process" Vol. 17C (1993) Abstract H123, Journal of Cellular Biochemistry, February 8-14, 1993, Taos, New Mexico.

Prunkard et al. (1996) "High-Level Expression Of Recombinant Human Fibrinogen In The Milk Of Transgenic Mice" Vol. 14, Nature Biotechnology, pp. 867-871.

Reddy et al., (1991) "Expression Of Human Growth Hormone In The Milk Of Transgenic Mice" Vol. 2, No. 1, Animal Biotechnology, pp. 15-29.

Redman, C., et al. (1991), "Recombinant Production, Secretion, And Clotting Behavior Of Fibrinogen And Cell Line Used Therein," Chemical Abstracts, p. 526.

Rixon, M.W., et al. (1985), "Nucleotide Sequence Of The Gene For The γ Chain Of Human Fibrinogen," Vol. 24, Biochemistry, pp. 2077-2086.

Rixon et al. (1983) "Characterization Of A Complementary Deoxyribonucleic Acid Coding For The α Chain Of Human Fibrinogen" Vol. 22, No. 13, Biochemistry, pp. 3237-3244.

Roy et al. (1991) "Assembly And Secretion Of Recombinant Human Fibrinogen" Vol. 266, No. 8, The Journal of Biological Chemistry, pp. 4758-4763.

Shani et al. (1992) "Expression Of Human Serum Albumin In The Milk Of Transgenic Mice" Vol. 1, No. 5, Transgenic Research, pp. 195-208.

Simons et al. (1988) "Gene Transfer Into Sheep" Vol. 6, Bio/Technology, pp. 179-183

Sinai Yarus et al., (1996) "Engineering Transgenes For Use In The Mammary Gland" Vol. 18, Genetic Engineering, pp. 57-81.

Storb et al. (1986) "Transgenic Mice With μ And κ Genes Encoding Antiphosphorylcholine Antibodies" Vol. 164, The Journal of Experimental Medicine, pp. 627-641.

Tojo et al., (1993) "Production And Characterization Of Transgenic Mice Expressing A hGH Fusion Gene Driven By The Promoter Of Mouse Whey Acidic Protein (mWAP) Putatively Specific To Mammary Gland" Vol. 39, No. 2, Journal of Reproduction and Development, pp. 145-155

Turner et al. (1992) "Proteins Are Secreted By Both Constitutive And Regulated Secretory Pathways In Lactating Mouse Mammary Epithelial Cells" Vol. 117, The Journal of Cell Biology, pp. 269-278

Velander et al. (1992) "High-Level Expression Of A Heterologous Protein In The Milk Of Transgenic Swine Using The cDNA Encoding Human Protein C", Vol. 89, Applied Biological Sciences, pp. 12003-12007.

Whitelaw et al. (1992) "Position-Independent Expression Of The Ovine β -Lactoglobulin Gene In Transgenic Mice" Vol. 286, Biochemical Journal, pp. 31-39.

Wilkins et al. (1992) "Isolation Of Recombinant Proteins From Milk" Vol. 49, Journal of Cellular Biochemistry, pp. 333-338.

Yu et al. (1984) "Fibrinogen Precursors" Vol. 259, No. 16, The Journal of Biological Chemistry, pp. 10574-10581.

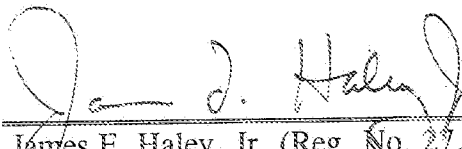
Yu et al. (1989) "Functional Human CD4 Protein Produced In Milk Of Transgenic Mice" Vol. 6, Mol. Biol. Med., pp. 255-261.

None of the above-cited documents, made of record by applicants herein, renders unpatentable, either alone or in any combination thereof, the pending claims of this reissue application. Applicants request that this Statement and the cited documents be made of record in this application.

This Statement is submitted more than three months from the application filing date but before the mailing date of the first substantive Office Action. In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee.

The Commissioner, however, is hereby authorized to charge payment of any fees required in connection with this Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this statement is transmitted herewith.

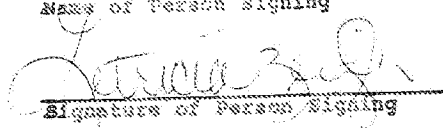
Respectfully submitted,


James F. Haley, Jr. (Reg. No. 27,794)
Attorney for Applicants
c/o FISH AND NEAVE
1251 Avenue of the Americas
New York, New York 10020
Telephone: (212) 596-9000

I hereby certify that this
Correspondence is being
Deposited with the U.S.
Postal Service as First
Class Mail in an Envelope
Addressed to: ASSISTANT
COMMISSIONER OF PATENTS
WASHINGTON D.C. 20231, on

2/11/99
LERRICIA ZEIGLER

Name of Person Signing


Signature of Person Signing